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January 5, 2006

Division of Dockets Management
Food and Drug Administration, Room 1061, (HFA-305)
5630 Fisher's Lane
Rockville, MD 20852

Docket Number 95S-0158 (BB IND #10,719)

RE: BB IND 10,719, POLY-SFH-P INJECTION [Polymerized Human Hemoglobin (Pyridoxylated), PolyHeme®], Protocol RTBSE-11-(N): Publicly Disclosed Information

Dear Sir:

Reference is made to our Investigational New Drug Application (IND) for Poly-SFH-P Injection for acute trauma, BB IND #10,719.

In conformance with 21 CFR 312.54(a) and the Draft Guidance for Industry entitled *Exception from Informed Consent Requirements for Emergency Research* (March 30, 2000) which require that Institutional Review Board (IRB) information concerning public disclosure be submitted to this Docket for clinical investigations involving an exception from informed consent [21 CFR 50.24(a)(7)(iii)], we provide documentation for the following sites in Albany, NY and Kansas City, KS:

Albany Medical Center

IRB: Western Institutional Review Board (WIRB)
3535 Seventh Ave. SW
Olympia, Washington, USA 98502-5010

University of Kansas Medical Center

IRB: Human Subjects Committee
University of Kansas Medical Center
3901 Rainbow Boulevard
Kansas City, KS 66160

95S-0158

SUP48

A copy of this submission is being submitted to BB IND #10,719.

If you have any comments or questions, please contact the undersigned at 847-864-3500.

Sincerely,

Eva Essig, PhD
Vice President, Regulatory Affairs and Quality